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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/521,622

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Takeshi Hagio

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EXAMINER

FERNANDEZ, SUSAN EMILY

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

10/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/521,622

Applicant(s)

HAGIO ET AL.

Examiner

Susan E. Fernandez

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1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 and 71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 and 71 is/are rejected.
- 7) ☒ Claim(s) 47 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>1/14/05, 4/9/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The amendment filed June 7, 2007, has been received and entered.

Claims 49-70 are cancelled. Claims 1-48 and 71 are pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-48 and 71, in the reply filed on June 7, 2007, is acknowledged.

Claims 1-48 and 71 are examined on the merits to the extent they read on the elected subject matter.

Claim Objections

Claim 47 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim may not serve as a basis for any other multiple dependent claim, either directly or indirectly. Claim 47 indirectly depends from claim 29, a multiple dependent claim. See MPEP § 608.01(n). Although the multiple dependent claim could technically be considered unexaminable, claim 47 has been further treated on the merits as if claim 29 depends from claim 27 (and thus claims 30-46 depend from claim 27).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-48 and 71 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 27 are rendered indefinite by the recitation "conditions capable of inducing electroporation." It is unclear whether electroporation actually takes place as one of the steps of the method given the use of the phrase "capable of." This phrase does not necessarily signify that electroporation occurs in the process. Furthermore, it is unclear where in the recited steps the transfer of nucleic acid occurs. Thus, claims 1-48 and 71 are rejected under 35 U.S.C. 112, second paragraph.

Claim 29 is also rendered indefinite by the recitation "conditions capable of inducing electroporation" for the same reasons described above. Thus, claims 29-48 and 71 are rejected under 35 U.S.C. 112, second paragraph.

The term "high" in claim 6 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what voltage range is considered "high."

Claim 27 is indefinite since it is unclear how the recited steps are for "producing a plant." It is even unclear whether the cell recited in steps a) and b) is a cell of a plant. Thus, claims 27-48 and 71 are rejected under 35 U.S.C. 112, second paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Dodgson et al. (WO 00/63407, listed on IDS).

Dodgson et al. discloses a method of introducing a substance into a cell, which can be the transfection of a cell (abstract). One embodiment of the invention is the introduction of DNA into living cells "...by rupturing or forming a discontinuity in the cell wall by the process of electroporation" (page 3, lines 20-21). Prior to the transfection of cells, the cells are sorted, and this can be achieved by directed pressure pulses (page 9, lines 1-5). Figure 4e shows an embodiment of the invention wherein pressure is applied to cells to be transfected. The cell is localized against the orifice of a channel which contains the transfection material by a force created by a pressure drop (page 14, line 20 through page 15, line 2). Furthermore, electrodes may be included to electroporate the cell membrane around the orifice of the channel (page 15, lines 9-10). Clearly Dodgson et al. teaches a method for transferring a nucleic acid into a cell, wherein first a pressure different from an atmospheric pressure is applied, followed by electroporation. Thus, instant claims 1 and 4 are anticipated.

Moreover, Dodgson et al. teaches that a microprocessor is used to modify one or more system parameters, including the pumping pressure (page 17, lines 17-18). Given that there is

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such a control on the pumping pressure, instant claims 2 and 3 (depressurization, pressurization) are taught by the reference.

A holding of anticipation is clearly required.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmukler (US 5,173,158).

Schmukler teaches a method of electroporation wherein cells are trapped into pores in a film with diameters smaller than the diameters of the cells, and an electric field is applied to cause electroporation of the trapped cells (column 1, line 60 through column 2, line 3). The cells can be trapped into the pores by pressure such as hydrostatic pressure head from a regulated pressure source or a vacuum source (column 3, lines 20-26). Clearly the pressure applied to the cells must be different from atmospheric pressure. Thereafter, a low voltage pulse is applied which causes electroporation of the cells (column 3, lines 27-34). It is noted that "when the pressure gradient across the film is negative, or decreases from a positive value, the trapped first type of cells will pull in material, such as genetic material (DNA)..." from a portion of the apparatus used to perform the Schmukler invention (column 3, lines 44-47). Therefore, Schmukler indeed teaches a method for transferring a nucleic acid into a cell which comprises steps recited in instant claim 1. Instant claim 4 is also anticipated. Given the pressure gradient, the cells are exposed to depressurization and pressurization, thus the reference anticipates instant claims 2 and 3.

A holding of anticipation is clearly required.

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Claims 1-5 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Rickwood (WO 01/05994, listed on IDS).

Rickwood discloses a method of introducing a substance into a cell wherein bubbles containing gas are generated in a liquid medium comprising the cell, and the bubble interacts with the cell to form a hole in the surface of the cell (page 2, last paragraph through page 3, first paragraph). The substance that can be introduced into a cell can be a nucleic acid (page 8, last paragraph). Transfection of the cells occurs at pressure below and above atmospheric pressure, such as a pressure of from 1×10^4 Pa to atmospheric pressure, and a pressure of 1×10^5 Pa or above (page 6, last paragraph). Thus, the cell is subjected to depressurization or pressurization, as required by instant claims 2 and 3. It is noted that 1×10^4 Pa can be considered "a pressure reduced by about 0.096 MPa from the atmospheric pressure" as required by instant claim 5. Finally, the Rickwood method can be performed on plant cells (page 9, first paragraph).

It is noted that the cell and the nucleic acid are placed under conditions "capable of inducing electroporation" given that the cell is maintained in a viable state. Note that the recitation of the step of "placing the cell and the nucleic acid under condition capable of inducing electroporation" in instant claim 1, does not require that electroporation takes place.

A holding of anticipation is clearly required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-48 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dodgson et al. in view of Gutierrez-Armenta et al. (US 2002/0046416).

As discussed above, Dodgson et al. anticipates claims 1-4. However, Dodgson et al. does not expressly disclose that the pressure applied to the treated cells is a pressure reduced by about 0.096 MPa from the atmospheric pressure, or that a "high" voltage pulse is applied to the cell and the nucleic acid in at least two directions.

Nevertheless, the selection of a specific suitable pressure, voltage pulse, and voltage pulse application directions, including that claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill, particularly since Dodgson et al. teaches varying the pressure applied (page 17, lines 2-3 and 17-18) and that the electrodes "...may advantageously be shaped in order to concentrate field and/or localize poration." Thus, claims 5 and 6 are rendered obvious.

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Furthermore, Dodgson et al. differs from the claimed invention in that it does not expressly disclose that the cell treated is a plant cell of the types recited in instant claims 10-26 wherein the steps can be performed on a seed, and that the treated plant cell differentiates/grows/multiplies and/or yields a plant which may not contain a somaclonal variation.

Gutierrez-Armenta et al. discloses that cell growth may be controlled by administering DNA to a cell, and that the DNA may be administered by electroporation of plant seed cells with DNA (page 2, paragraph [0015]).

At the time the invention was made, it would have been obvious to have practiced the invention on plant cells, which can be contained in seeds, to produce plants which may not contain a somaclonal variation. One of ordinary skill in the art would have been motivated to do this since electroporation has been found to be suitable for administering DNA to plant seed cells, and therefore, there would have been a reasonable expectation of success in transferring nucleic acid into plant cells to produce a plant by the methods of Dodgson et al. which uses electroporation for nucleic acid transfer into cells. Moreover, there would have been a reasonable expectation of success in transferring nucleic acids into cells of plants of the types recited in the instant claims to yield the predictable result of producing these plants.

Thus, a holding of obviousness is clearly required.

Claims 1-48 and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schmukler in view of Gutierrez-Armenta et al.

As discussed above, Schmukler anticipates claims 1-4. However, Schmukler does not expressly disclose that the pressure applied to the treated cells is a pressure reduced by about 0.096 MPa from the atmospheric pressure, or that a "high" voltage pulse is applied to the cell and the nucleic acid in at least two directions.

Nevertheless, the selection of a specific suitable pressure, voltage pulse, and voltage pulse application directions, including that claimed, would have been an obvious matter of optimization on the part of the artisan of ordinary skill, particularly since Schmukler teaches regulation of pressure applied (column 3, lines 20-26). Thus, claims 5 and 6 are rendered obvious.

Furthermore, Schmukler differs from the claimed invention in that it does not expressly disclose that the cell treated is a plant cell of the types recited in instant claims 10-26 wherein the steps can be performed on a seed, and that the treated plant cell differentiates/grows/multiplies and/or yields a plant which may not contain a somaclonal variation.

Gutierrez-Armenta et al. discloses that cell growth may be controlled by administering DNA to a cell, and that the DNA may be administered by electroporation of plant seed cells with DNA (page 2, paragraph [0015]).

At the time the invention was made, it would have been obvious to have practiced the invention on plant cells, which can be contained in seeds, to produce plants which may not contain a somaclonal variation. One of ordinary skill in the art would have been motivated to do this since electroporation has been found to be suitable for administering DNA to plant seed cells, and therefore, there would have been a reasonable expectation of success in transferring nucleic acid into plant cells to produce a plant by the methods of Schmukler which uses

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electroporation for nucleic acid transfer into cells. Moreover, there would have been a reasonable expectation of success in transferring nucleic acids into cells of plants of the types recited in the instant claims to yield the predictable result of producing these plants.

Thus, a holding of obviousness is clearly required.

Claims 1-5, 7-48, and 71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rickwood in view of Gutierrez-Armenta et al.

As discussed above, Rickwood anticipates claims 1-5 and 7. However, Rickwood differs from the claimed invention in that it does not expressly disclose that the cell treated on is a plant cell of the types recited in instant claims 10-26 and wherein the steps can be performed on a seed, and that the treated plant cell differentiates/grows/multiplies and/or yields a plant which may not contain a somaclonal variation.

Gutierrez-Armenta et al. discloses that cell growth may be controlled by administering DNA to a cell, and that the DNA may be administered by electroporation of plant seed cells with DNA (page 2, paragraph [0015]).

At the time the invention was made, it would have been obvious to have practiced the invention on plant cells, which can be contained in seeds, to produce plants which may not contain a somaclonal variation. One of ordinary skill in the art would have been motivated to do this since DNA can indeed be transferred to seeds, and therefore, there would have been a reasonable expectation of success in transferring nucleic acid into plant cells in seeds to produce a plant by the methods of Rickwood which teaches nucleic acid transfer into cells. Moreover, there would have been a reasonable expectation of success in transferring nucleic acids into cells

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of plants of the types recited in the instant claims to yield the predictable result of producing these plants.

Thus, a holding of obviousness is clearly required.

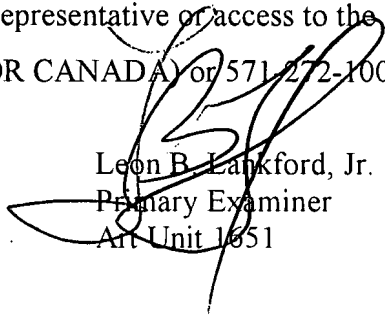
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan E. Fernandez whose telephone number is (571) 272-3444. The examiner can normally be reached on Mon-Fri 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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